Rulemaking for Methylene Chloride and N-Methylpyrrolidone (NMP) under the Toxic Substances Control Act (TSCA)

Panel Outreach

June 15, 2016

ED_001625_00032151-00001

Today's Discussion

- Background:
  - Consultation with Small Entity Representatives
  - TSCA Work Plan for Chemical Assessments
- Methylene Chloride and N-methylpyrrolidone (NMP)
- Toxic Substances Control Act (TSCA) Section 6(a)
  - Background
  - Developing the Regulations
- Affected entities and potential compliance costs
- Contact information
- Appendices

ED_001625_00032151-00002

Background: Consultation with Small Entity Representatives

- EPA is interested in not only information, but also advice and recommendations from the small entity representatives (SERs)
- EPA will use this information to develop a regulatory flexibility analysis, which becomes part of the record for the potential regulation
- Key elements in this analysis:
  - Number of small entities to which the potential rule would apply
  - Projected compliance requirements of the potential rule
  - Identification of all relevant Federal rules which may duplicate, overlap or conflict with the potential rule
  - Any significant alternatives to the potential rule which accomplish the stated objectives and which minimize significant economic impact of the potential rule on small entities

ED_001625_00032151-00003

SERs and the Regulatory Process

- We are seeking information on how the options presented might impact your business or organization
  - Provide specific examples of impacts
  - Provide cost data, if available
  - Please see detailed questions in Appendix A
- We are also seeking alternative methods of regulating these risks
  - Suggest other relevant options, including data costs and information on how to ensure compliance
  - Suggest ways that small businesses could benefit from flexibilities, such as different compliance timetables, simplified reporting requirements, and exemptions
- We would like to minimize duplication
  - Provide information on any duplicative or contradictory Federal regulations you are aware of
  - For a list of existing regulations, please see Appendix B

ED_001625_00032151-00004

SERs and the Regulatory Process

- On March 17, 2016, EPA held a pre-panel meeting with SERs to discuss the rulemaking process and how the regulatory options may impact their businesses
- In response to your comments, we:
  - Provided requested follow-up information
  - Have added clarifying information to this presentation and additional information in the appendices
  - Have added your feedback to this presentation

ED_001625_00032151-00005

Background: TSCA Work Plan for Chemical Assessments

- EPA has identified a subset of existing chemicals as a high priority for risk assessment
- 2012-2013:
  - With input from stakeholders, EPA identified a subset of chemicals for assessment, known as the TSCA Work Plan, and described the methodology for how they were prioritized
  - Performed problem formulation for five Work Plan chemicals, developed draft risk assessments for peer review, and released them for public comment.

ED_001625_00032151-00006

Background: TSCA Work Plan for Chemical Assessments

- 2014-2015:
  - Released first final risk assessments (TCE, methylene chloride, NMP, antimony trioxide, HHCB)
    - No risks found for uses assessed for antimony trioxide and HHCB.
    - Risks found for uses assessed for TCE, methylene chloride, and NMP. Risk management process began.
  - Refreshed Work Plan with updated exposure information; currently contains 90 chemicals
- 2015-2016:
  - Problem formulation and data needs assessment issued for several flame retardant clusters
  - Problem formulation issued for 1,4-Dioxane
  - Draft risk assessment for 1-bromopropane released for public comment

ED_001625_00032151-00007

Overview: Methylene Chloride and NMP

- EPA assessed Methylene Chloride and NMP paint removal uses as part of the TSCA Work Plan for Chemical Assessments.
- Methylene Chloride
  - Volatile, colorless liquid, non-flammable, non-explosive, non-corrosive, inexpensive.
  - Used frequently as a solvent; also in adhesives, metal cleaning, chemical processing, pharmaceuticals.
  - 25% of methylene chloride in the US used in paint removers (66.3 million lbs annually), down from 50% in 1980s.
- NMP
  - Mildly volatile, colorless liquid, low flammability, non-explosive.
  - Used frequently as a solvent; also in adhesives, leather and brush cleaners, manufacturing of circuit boards, pesticides, petrochemical processing.
  - 9% of NMP in the US used in paint removers (16.6 million lbs annually).
  - Frequently an alternative to methylene chloride paint removers.

ED_001625_00032151-00008

	Methylene Chloride Key Information	NMP Key Information
Notes on Use	Used for decades; nonflammable; works quickly Cause of death for ~1 worker/year during bathtub refinishing + suspected additional deaths during other paint removal jobs (see Appendix F) Inhalation exposure; extremely volatile	Marketed as safer & greener than methylene chloride Works more slowly Exposure is primarily dermal, but also via inhalation
Manufacturers & Users	2 manufacturers, 7 product formulators 5,000 workers in graffiti removal & other outdoor uses 8,000 workers as home contractors (including 1,300 bathtub refinishers) 32,000 workers in commercial/industrial facilities 2.4 million consumer users	6 manufacturers, 14 product formulators 46,000 workers in graffiti removal & other outdoor uses 7,000 workers as home contractors 1,400 workers in commercial/industrial facilities 1.4 million consumer users
Health Effects and Risks of Concern	Acute effects: Neurotoxicity - confusion, incapacitation, and death Chronic effects: Cancer and liver toxicity Inhalation exposures are 2-3 orders of magnitude from target benchmarks Risks for bystanders due to inhalation exposures	Concern is for women of child-bearing age High dose acute effects: Fetal death Lower dose chronic effects (developing fetus): Low birthweight, delayed ossification, growth retardation.
Substitutes	Alternative processes (Heat guns, mechanical sanding, hydroblasting, media blasting (starch, soda, etc.)) Chemical substitutes (Benzyl alcohol, dibasic esters, acetone-toluene-methanol formulations, caustics) Generally, hazards of substitutes are of less concern (See Appendix D)	
Notable Regulations	OSHA PEL 25 ppm Banned for graffiti use in 12 states Listed under California Safer Consumer Products regulation Prohibited for residential & consumer use in the EU	No OSHA PEL California PEL 1 ppm + gloves On the EU candidate list of substances of very high concern

Risk Assessment: Methylene Chloride

- Final TSCA Work Plan Chemical Risk Assessment: August 2014
  - Followed Agency peer review process of publishing a public draft, peer review, and response to peer review and public comment
- Risk assessment identified inhalation risks from paint removers containing methylene chloride:
  - Chronic exposure effects: cancer and liver toxicity
  - Acute exposure effects: Neurotoxicity - confusion, incapacitation, and death
  - Risks from chronic (lifetime) exposure in majority of scenarios except when personal protective equipment (respirator) is worn in low exposure scenarios.
  - Risks from acute high-end exposure (small, enclosed room with poor ventilation, such as a bathroom).
  - Risks to non-users (bystanders and adjacent workers) except in lowest exposure scenarios.
- See: http://www.epa.gov/assessing-and-managing-chemicals-under-tsca/assessments-tsca-work-plan-chemicals#dcm

ED_001625_00032151-00010

Risk Assessment: Methylene Chloride

- Risks were identified for most worker and consumer exposure scenarios.
- For **non-cancer risks** a **margin of exposure** (MOE) method was used to determine the presence or absence of risk for both acute and chronic exposure scenarios.
  - The benchmark MOE used in the methylene chloride risk assessment is 10.
    - This benchmark constitutes 3x residual uncertainty in extrapolating from animals and 3X residual uncertainty for variability in humans
  - People exposed are considered to be at risk when MOEs are below the benchmark MOE of 10.
  - MOEs and risks calculations for non-cancer effects are explained on the next slide
- For **cancer risks**, the inhalation unit risk (IUR) was used to estimate excess cancer risks for inhalation occupational exposure scenarios.
  - The excess cancer risk is the product of the exposure concentration and the IUR
  - Protecting against non-cancer risks protects against these cancer risks
  - Risk calculations for cancer are explained on the next slide

Risk Calculation (Non-Cancer)

Non-Cancer MOE compared to benchmark MOE (uncertainty factors, or UFs)

$$\text{MOE (acute or chronic)} = \frac{\text{Non-Cancer Hazard Value (Point of Departure)}}{\text{Human Exposure (ppm)}}$$

Where: Hazard Value

POD = Human equivalent dose (ppm)

MOE = Margin of exposure (unitless)

- **The lower the exposure the higher the MOE.**
- **The *lower* the calculated MOE value, the *higher* the risk**
- **Cause for concern increases the lower the scenario's risk value (MOE) is below the benchmark MOE**

Risk Calculation (Cancer)

Cancer

Risk = Human Exposure X IUR

Where:

- Risk = Cancer risk (unitless)
- Human exposure = Exposure estimate (LADC in ppm) from occupational exposure assessment
- IUR = inhalation unit risk (a x 10* ppm)

*** The *higher* the calculated risk value, the higher the risk**

*** Cause for concern increases the more the scenario's cancer risk value is above the cancer benchmark**

ED_001625_00032151-00013

Methylene Chloride Exposure Estimates

- SERs mentioned that they feel that their workplace exposures to methylene chloride are a shorter duration that what is described in the risk assessment
- The risk assessment describes various scenarios using an 8-hour time weighted average approach
  - Estimates consider each industry/activity separately to represent the best estimate of exposures during an 8-hour work shift from activities specific to that industry/scenario, **even if workers are using the chemical for less than 8 hours**
  - Air concentrations were identified for each industry/activity from literature sources and these data were normalized to an 8-hour time weighted average (8-hr TWA)

ED_001625_00032151-00014

Risk Estimates: Methylene Chloride

Industry	Benchmark MOE (acute & chronic)	MOE acute exposure	MOE chronic exposure, non-cancer	Cancer estimate
Professional Contractors	10	**0.015**	**0.050**	**1.9 in 1,000**
Automotive Refinishing	10	**0.11**	**0.34**	**2.9 in 10,000**
Furniture Refinishing	10	**0.035**	**0.13**	**7.7 in 10,000**
Aircraft Paint Stripping	10	**0.012**	**0.039**	**2.5 in 1,000**
Graffiti Removal	10	**0.037**	**0.16**	**6.3 in 10,000**
Other workplace settings (immersion stripping)	10	**0.0063**	**0.021**	**4.6 in 1,000**

The lower this number is below 10, the greater the risk (numbers above 10 indicate no non-cancer risks of concern)

The larger this number is, the greater the risk

Acceptable Exposure Limit (AEL): Methylene chloride

Exposure Estimates: Methylene Chloride

Industry	Acceptable exposure limit (8 hr TWA, ppm)	Acute high-end estimated exposure (8 hr TWA, ppm)	**Chronic high-end estimated exposure (8 hr TWA** ppm)
Professional Contractors	**0.2**	858	431
Automotive Refinishing	**0.2**	120	64
Furniture Refinishing	**0.2**	364	169
Aircraft Paint Stripping	**0.2**	1,095	551
Graffiti Removal	**0.2**	342	139
Other workplace settings (immersion stripping)	**0.2**	2,015	1009

ED_001625_00032151-00017

Risk Assessment: NMP

- NMP is often marketed as a “safer” alternative to Methylene Chloride
- Final TSCA Work Plan Chemical Risk Assessment: March 2015
  - Followed Agency peer review process of publishing a public draft, peer review, and response to peer review and public comment
- Risk assessment identified dermal (liquid or vapor through skin) and inhalation exposure risks from the use of paint removers containing NMP:
  - Developmental effects (acute: fetal mortality; chronic: reduced fetal body weight). Concern is for women of child-bearing age.
  - Chronic exposure risks if used:
    - More than 8 hours per day for more than 5 consecutive days, even if specialized protective gloves are worn
    - More than 4 hours per day, for more than 5 consecutive days, if specialized protective gloves are not worn
  - Acute exposure risks if used:
    - More than 8 hours on a single day, even if specialized protective gloves are worn
    - More than 4 hours on a single day, if specialized protective gloves are not worn
  - No risks to bystanders
- See http://www.epa.gov/assessing-and-managing-chemicals-under-tsca/assessments-tsca-work-plan-chemicals#completed

ED_001625_00032151-00018

Risk Assessment: NMP

- Risks were identified for a number of worker and consumer exposure scenarios.
  - No risks identified for workers or residents who may be located nearby those that are working with NMP-based paint removers.
- To determine the presence or absence of non-cancer risks for both **acute and chronic exposures**, the **margin of exposure** (MOE) method was used to evaluate the risk
  - The benchmark MOE used for the NMP risk assessment is 30.
    - This benchmark constitutes 3x residual uncertainty in extrapolating from animals and 10X residual uncertainty for variability in humans
  - All users exposed are considered to be at risk when MOEs are below the benchmark MOE of 30.
  - See earlier slide for an explanation of MOEs and risks calculations for non-cancer effects

ED_001625_00032151-00019

Risk Estimates: NMP

Scenario (covers several industries, assumes no gloves used)	Benchmark MOE (acute & chronic exposure)	MOE– acute exposure	MOE chronic exposure, non-cancer effects
Miscellaneous stripping Assumed mostly indoor, high end of range 1.0 weight fraction 890 cm^2 skin surface area, 8 hours	30	**0.7**	**0.1**
Graffiti removal Assumed mostly outdoor but may include semi-confined spaces, high end of range 1.0 Weight fraction 890 cm^2 Skin surface area, 8 hours	30	**0.7**	**0.1**
Miscellaneous stripping Assumed mostly indoor, mid end of range 0.625 weight fraction, 668 cm^2 skin surface area, 4 hours	30	**13.7**	**5.4**
Graffiti removal Assumed mostly outdoor but may include semi-confined spaces, mid end of range 0.625 weight fraction, 668 cm^2 skin surface area, 4 hours	30	**14.1**	**6.1**

The lower these numbers are from 30, the greater the risk (numbers above 30 indicate no risks of concern)

ED_001625_00032151-00020

Acceptable Exposure Limit (AEL): NMP

From Risk Assessment to Risk Reduction

Risks identified

- Methylene chloride and NMP found to pose risks when used in typical commercial and consumer scenarios

Risk reduction needed

- Methylene chloride: Exposures are 100 to 1,000 times greater than acceptable exposure levels
- NMP: Exposures are 5 – 10 times greater than acceptable exposure levels

Approach chosen

- Regulation under TSCA Section 6(a) is the approach most likely to reduce risks to workers and consumers

Background: TSCA Section 6(a)

- Provides EPA with the authority to prohibit or limit the manufacture, processing, distribution in commerce, use or disposal of a chemical or mixture.
- EPA must make certain findings before a section 6(a) rule may be finalized:
  - There is a reasonable basis to conclude that a chemical substance or mixture "presents or will present an unreasonable risk of injury to health or the environment."
  - The regulatory option chosen is the least burdensome option that adequately protects against such risk.

ED_001625_00032151-00023

Options Under TSCA Section 6(a)

- Prohibit or limit manufacture, processing or distribution in commerce.
- Prohibit or limit for particular use or above a set concentration.
- Require warnings and instructions.
- Require recordkeeping and testing.
- Prohibit or regulate manner or method of commercial use.
- Prohibit or regulate manner or method of disposal.
- Direct manufacturers/processors to give notice of risk to distributers and users and replace or repurchase.

ED_001625_00032151-00024

EPA's Authority to Regulate Occupational Risks

- SERs were interested in more information about EPA's authority to regulate occupational hazards and risks, compared to OSHA
- OSHA authority extends only to private sector employers
  - Public sector employees conducting paint removal are not subject to OSHA
- TSCA restrictions are consistent with OSHA hierarchy of hazard control (eliminate/substitute hazard; engineering controls; best practices administrative controls; personal protective equipment)
- TSCA authority can address the risks form methylene chloride and NMP in paint removal that cut across worker, public sector and consumer settings
- EPA is working closely with OSHA; both agencies feel TSCA is the appropriate authority to address the risks that EPA has identified, including those that occur in workplaces
  - See letter of support from Department of Labor in Appendix E

ED_001625_00032151-00025

Uses Under Consideration

- Uses considered for regulation under TSCA Section 6(a) are commercial and consumer paint removers containing methylene chloride or NMP.
- Examples of small business uses:
  - Automotive, aircraft, and marine craft body paint, and interior repair and maintenance
  - Flooring contractors
  - Furniture repair and refinishing
  - Painting and wall covering contractors
  - Bathtub refinishing

ED_001625_00032151-00026

Potentially Impacted Sectors

- Ship building and repairing
- Aircraft manufacturing and repairing
- Museums
- Independent artists, writers, and performers
- Automotive body, paint, and interior repair and maintenance
- Flooring contractors
- Reupholster and furniture repair
- Painting and wall covering contractors
- Paint remover processors or formulators

ED_001625_00032151-00027

Developing Potential Regulatory Options

- Over the past year, EPA has identified regulatory options under Section 6(a) of TSCA that would provide adequate protection from the risks identified
- Stakeholders we've been working with:
  - Affected States and Tribes
  - Chemical manufacturers, product formulators, and their trade associations
  - Commercial paint remover users in various sectors
- Generally, alternatives are available and have been evaluated for use in several industries (automotive, renovations/contracting/decorating, marine, graffiti removal, and aircraft)
  - As SERs and other stakeholders have reported, alterative methods and chemical substitutes are already in use
  - See Appendices D and G for more information on substitutes

ED_001625_00032151-00028

Developing Potential Regulatory Options

- What we've heard, from stakeholders, from industry research, and from SERs in our last meeting:
  - Marinecraft:
    - Paint is generally not removed to the substrate; when needed, sand or soda blasting are used.
    - Chemical stripping requires consideration of disposal (heavily regulated near water).
  - Aircraft:
    - Use of methylene chloride is declining, particularly among large scale users, due to air regulations and other considerations.
    - Refinishing of small aircraft still use methylene chloride, though many now use benzyl alcohol formulations.
  - Renovations and contractors:
    - Many firms have stopped using methylene chloride due to worker safety concerns, potential for fatal accidents, odor (employee and client complaints), and specialized PPE, training, and waste disposal needed.
    - Some firms use MC only outdoors or with fans for ventilation
    - Alternatives identified tend to be mechanical methods or benzyl alcohol; alternatives can take longer than methylene chloride to complete a job.
    - Certain wood substrates can be damaged by mechanical methods and require chemical stripping.
  - Automotive (collision repair and autobody):
    - Chemical removers do not appear to be critical for this sector as industry reps reported large use of abrasives for paint removal.
  - Furniture refinishing:
    - Seem to exclusively use methylene chloride, with some attempts at alternatives containing acetone.
    - There are flammability concerns with substitutes given the prevalence of wood substrates.
    - Certain wood substrates can be damaged by mechanical methods and require chemical stripping.
  - Manufacturers:
    - Some SERs say that methylene chloride costs less than NMP or other paint removers.
    - Limiting sales of methylene chloride to 55-gal drums could be cost-prohibitive for small businesses.

ED_001625_00032151-00029

Substitute Chemicals and Alternative Methods

- EPA has learned about successful use of substitute chemicals and alternative methods for many types of paint and coating removal with methylene chloride or NMP
  - Chemical substitutes include: Benzyl alcohol, dibasic esters, acetone-toluene-methanol formulations, and caustics
  - Alternative processes include: Heat guns, mechanical sanding, hydroblasting, media blasting (starch, soda, etc)
- Generally, hazards of substitute chemicals or alternative methods are of less concern
- Information on successful substitutes was obtained from public reports, presentations at conferences, industry research and ongoing discussions with stakeholders
- See Appendices D and G for more information on substitutes

ED_001625_00032151-00030

Analyzing Potential Regulatory Options for Methylene Chloride

- From over 50 options analyzed, the two options presented today would provide risk reduction to target benchmarks
- Other options that EPA considered **do not** reduce exposure to benchmark risk levels

Option	Why it does not provide sufficient risk reduction
Limiting concentration of methylene chloride in a formulation	Even when reduced to 5% concentration, for typical work scenarios (>4 hours), workers would be at acute risk
Prohibiting certain formulations (such as spray) to reduce inhalation exposure	Most acute and cancer risk would remain.
Requiring local exhaust or other ventilation (without personal protective equipment)	Alone, ventilation does not reduce exposures to benchmark risk levels.
Requiring PPE at APFs lower than 1,000 or 10,000 (methylene chloride only)	1) Only air-supplied respirators can effectively reduce exposures 2) Below APF 1,000, exposures are not reduced to benchmark risk levels.

Continued on next slide

Analyzing Potential Regulatory Options for Methylene Chloride

Continued from previous slide

Option	Why it does not provide sufficient risk reduction
Requiring record keeping and testing	Alone, this does not provide protection from risks
Requiring labeling of products	The particular actions the label would need to require are not likely to be followed properly. The nature of the information the user would need to read, understand, and act upon is extremely complex. Rather than a simple message, the label would need to explain a variety of inter-related factors, including but not limited to the use of local exhaust ventilation, and respirators and assigned protection factor, as well as effects to bystanders. It is unlikely that label language changes will result in widespread, consistent, and successful adoption of risk reduction measures by users. For an example, see the Riley, et al. article referenced in Appendix F. As a result, exposures would not be reduced to benchmark risk levels.

ED_001625_00032151-00032

Potential Regulatory Options - Methylene Chloride

1. Regulatory Option #1: Prohibit manufacturing, distribution, and use of methylene chloride as a paint remover
2. Regulatory Option #2: Allow certain commercial uses with worker protections and other requirements to protect the public

- Worker protections: Personal protective equipment (PPE) or air exposure limit
  - PPE:
    - APF 1,000 would be in most scenarios, with APF 10,000 when immersion methods of paint removal are used. APF is the workplace level of respiratory protection that a respirator or class of respirators is expected to provide to employees.
    - A respiratory protection program includes training, medical monitoring, re-fitting, and other components of respirator protection programs
    - Workers nearby (occupational bystanders) would be required to wear respirators as well, or be excluded from the area
  - As an alternative, work places could meet an **air exposure limit** of 0.2 ppm
    - Potentially could use engineering controls such as ventilation to reduce the respirator APF needed
- Other requirements:
  - Downstream notification by manufacturers, processors, and distributors of the prohibitions for this use
  - Packaging of paint removers containing methylene chloride in volumes no less than 55-gallon drums
  - Bystanders (such as residents of homes) must stay out for up to 24 hours after work is completed

Risk Reduction of Potential Regulatory Options - Methylene Chloride

Reg. Option #	Regulatory Option description	Risk Reduction as a Result
1	Prohibit manufacturing, distribution, and use of methylene chloride as a paint remover	Risks eliminated. This option provides complete risk reduction.
2	Allow certain commercial uses with worker protections (such as PPE) and other requirements to protect the public (such as bystander exclusion)	- Eliminates risks for bystanders (residents of homes, for example) because they are excluded from the area - Assuming that PPE is used as required for efficacy, this reduces risks to benchmarks for workers and for occupational bystanders (other workers). See additional details on next slides.

ED_001625_00032151-00034

Risk Reductions: Methylene Chloride PPE Option

(Regulatory Option #2)

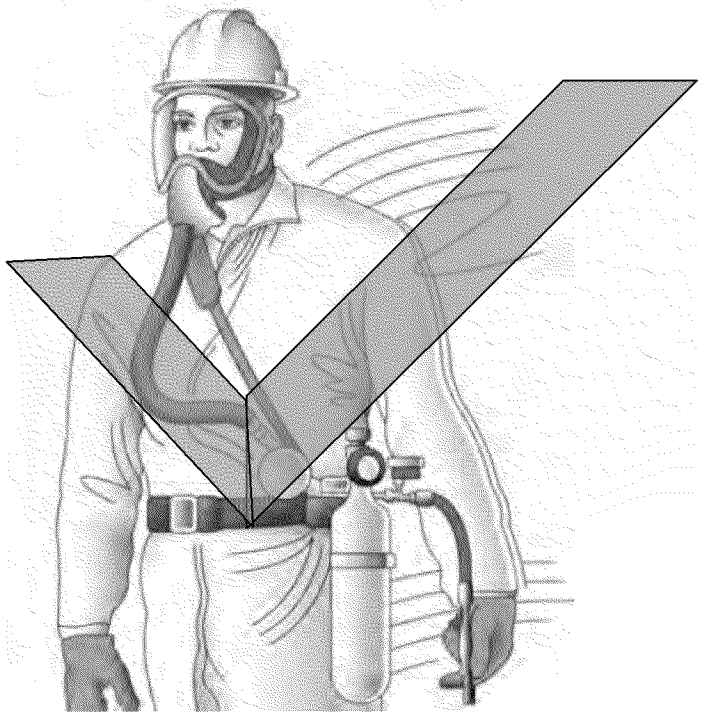
Industry	Benchmark MOE (acute & chronic exposure)	APF 1,000 Risk estimate – acute	APF 1,000 Risk estimate – chronic non-cancer	APF 1,000 Cancer estimate
Professional Contractors	10	**15**	**50**	**1.9 in 1,000,000**
Automotive Refinishing	10	**110**	**337**	**2.9 in 10,000,000**
Furniture Refinishing	10	**35**	**128**	**7.7 in 10,000,000**
Aircraft Paint Stripping	10	**12**	**39**	**2.5 in 1,000,000**
Graffiti Removal	10	**37**	**156**	**6.3 in 10,000,000**
Other workplace settings (immersion stripping) *(APF 10,000 or 1,000 + ventilation)*	10	**63** *(APF 10,000)*	**215** *(APF 10,000)*	**4.6 in 10,000,000** *(APF 10,000)*

All these numbers are now above 10, indicating no non-cancer risks of concern

All these numbers now indicate no cancer risks of concern

Examples of Air Supplied Respirators

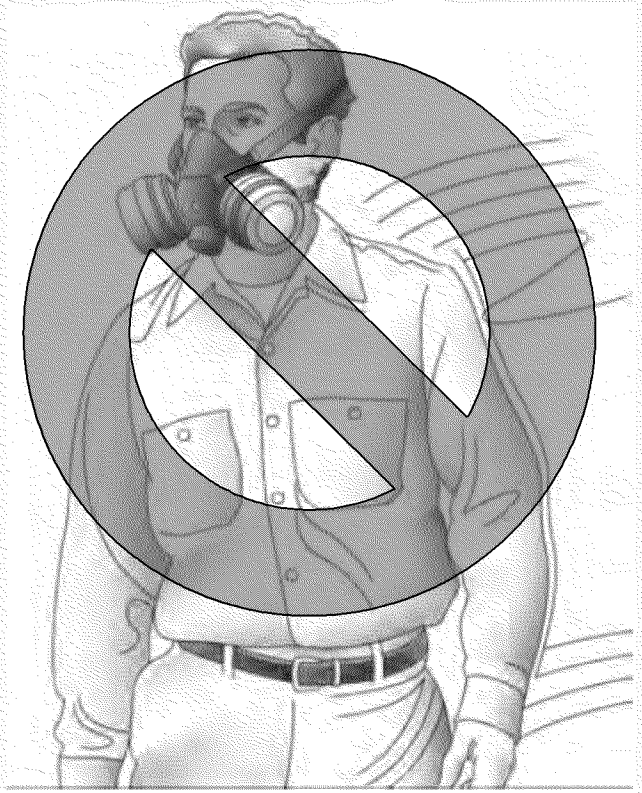
Half mask/Dust mask
APF=10
Needs to be fit tested



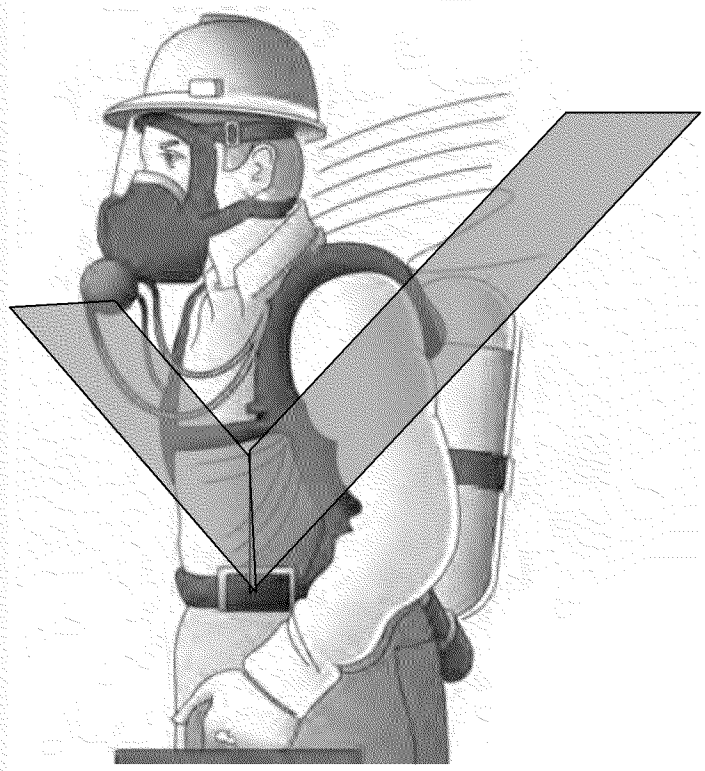
Full Facepiece Supplied-Air Respirator (SAR) with an auxiliary Escape Bottle
APF=1,000
APF = 10,000 (if used in "escape" mode)
Needs to be fit tested

For more information, see Appendix H or https://www.osha.gov/Publications/3352-APF-respirators.pdf

Examples of Air Supplied Respirators



Half mask (Elastomeric)
APF=10
Needs to be fit tested



Full Facepiece Self-Contained Breathing Apparatus (SCBA)
Pressure demand mode is APF=10,000
Needs to be fit tested

For more information, see Appendix H or https://www.osha.gov/Publications/3352-APF-respirators.pdf

Costs: Methylene Chloride Prohibition

(Regulatory Option #1)

- Costs include costs to manufacturers, processors and to commercial users
- Changing products to remove methylene chloride (chemical substitution in formulation, relabeling, and other changes) *(applies to manufacturers, processors)* + downstream notification about prohibited uses *(applies to manufacturers, processors, distributors)*
  - 2 manufacturers, 9 formulators
  - First-year costs: $260,000, or annualized cost: $17,000 (over 20 years)
- Costs associated with switching to substitutes *(commercial users)*
  - Process change
    - For some firms this is expected to be minimal if they have experience with using alternative chemicals or paint removal methods.
    - Other firms will likely have a trial and error period until they find an alternative chemical or mechanical means that meets the needs of their work process.
  - Hazards of substitutes
    - Substitutes present some hazards, but generally less than methylene chloride.
  - Job time when using substitutes *(all users)*. This is a cost or savings, depending on job specifics
    - Depending on the job, the time needed could increase or decrease. This is based on the type and number of coatings, surface prep, clean-up, dwell time, and other factors.
- **Total cost (for all commercial entities):**
  - **$17,000 per year** + qualitative inconvenience, hazards of substitutes, and increased time
  - First year monetized costs: $260,000

ED_001625_00032151-00038

Compliance Strategies: Methylene Chloride Prohibition

(Regulatory Option #1)

Sector	% Adopting Each Alternative											
	Benzyl alcohol	ATM	Other chemical strippers [a]	Caustic Strippers	DBE	Hand/ power sanding	Media blasting	Needle Gun/ Needle Scaler	Power Washing	Heat tools	Laser	Other [b]
Aircraft stripping	70%	0%	0%	0%	0%	0%	25%	0%	0%	0%	0%	5%
Bathtub refinishing	90%	0%	0%	0%	0%	10%	0%	0%	0%	0%	0%	0%
Professional contractors	10%	10%	0%	10%	10%	10%	10%	10%	10%	10%	10%	0%
Ship paint stripping	45%	0%	0%	0%	0%	45%	5%	0%	0%	5%	0%	0%
Graffiti removal	0%	0%	90%	0%	0%	0%	8%	0%	0%	0%	0%	2%
Consumer	23%	23%	0%	23%	23%	3%	0%	3%	3%	3%	0%	0%

Source: (IRTA, 2015).

a. This category includes a wide range of alternative chemical graffiti removers.

b. For Graffiti removal, "other" includes users who find they don't need to use graffiti removers or blasting systems and they would convert to other technologies. The dominant technology they would adopt would be painting over.

Compliance Strategies: Methylene Chloride Prohibition

(Regulatory Option #1)

- EPA currently assumes there is a viable chemical or mechanical alternative for industry sectors with the exception of the furniture refinishing industry
  - We are seeking information to confirm or change these assumptions
- Current cost estimates show a cost **savings** per firm when switching from methylene chloride to an alternative paint remover method in some industry sectors (aircraft, marine craft, automotive, and art conservation)
  - On a per ounce basis, some chemical alternatives are less expensive (e.g. caustic, acetone-toluene-methanol mixtures) than methylene chloride, which generates cost savings when purchasing a cheaper alternative
  - In some situations, less of the alternative product is needed (compared with methylene chloride) for the same job (example: benzyl alcohol products) so even if this alternative is cheaper, less is purchased, resulting in an overall cost savings

ED_001625_00032151-00040

Costs: Methylene Chloride Prohibition

(Regulatory Option #1)

Industry Sector	Total Annualized Cost	Total Annualized Cost Savings	Cost Per Small Firm	Cost Savings Per Small Firm
Aircraft	-	$447,000	-	$307
Art Rest/Con	-	$65,000	-	$7
Automotive	-	$408,000	-	$122
Bathtub Refinishing	$747,000	-	$965	-
Furniture Refinishing	Currently unquantified	-	Currently unquantified	-
Graffiti Removal	$123,000	-	$497	-
Profess Con.	$2,400,000	-	$1,046	-
Marine Craft	-	$1,300,000	-	$1,430

ED_001625_00032151-00041

Costs: Methylene Chloride Prohibition

(Regulatory Option #1)

- Manufacturers: Are the cost estimates for reformulation accurate?
- Users:
  - What quantities do you purchase? (gallon containers, 55-gallon drums, etc.) Would a requirement to purchase material in a 55-gallon drum significantly affect your business?
  - If paint removers containing methylene chloride or NMP were not available, what would the impacts be on your business?
- SERs mentioned that EPA's estimate of material change costs is inaccurate, and that most substitute products are more expensive.
  - Can you provide any more detailed information about this?
  - For anyone who has switched to substitutes, what were the impacts on your bottom line?

ED_001625_00032151-00042

Costs: Questions for Furniture Refinishing Industry

- How significant is paint or coating removal to your business overall?
  - If you could no longer use methylene chloride to remove paint/coatings what percentage of your annual revenue would be lost?
  - Would you be forced to close your firm if methylene chloride was banned from being used in paint removers?
  - Would you still be able to perform other types of furniture restoration that does not involve the use of paint removers?
  - Could alternative chemical strippers or mechanical methods be used on a portion of the paint removing jobs you currently perform, if so, what percentage?

ED_001625_00032151-00043

Costs: Methylene Chloride PPE

(Regulatory Option #2)

- Costs include costs to manufacturers, processors and to users
- Downstream notification about prohibited uses *(manufacturers, processors, distributors)*
  - 2 manufacturers, 9 formulators
  - First-year costs: $2,000, or annualized cost: $60 (over 20 years)
- Commercial users (total costs and for small businesses)
  - Total Annualized Cost: $33.6 million
    - Cost per employee of worker PPE of air supplied respirator (APF 1,000 except for immersion stripping which requires APF 10,000)
      - Device & fitting costs included ($1,486 to $2,128 per worker, per year varies by APF)
      - PPE training costs included ($252 per worker, per year)
      - Medical monitoring costs included ($212 per worker, per year)
    - Other engineering, equipment changes, or LEV controls would be applicable under this option but are not included in the cost estimate due to lack of data
  - If work is performed in a residence, homeowners are not permitted in the home while work is performed and for a period of at least 24 hours after work is completed

ED_001625_00032151-00044

Costs: Methylene Chloride PPE

(Regulatory Option #2)

Industry Sector	Total Annualized Cost	Cost Per Small Firm
Aircraft	$289,000	$1,095
Art Restoration & Conservation	$94,000	$1,026
Automotive	$366,000	$1,020
Bathtub Refinishing	$1,591,000	$1,056
Furniture Refinishing	$11,930,000	$1,005
Graffiti Removal	$237,000	$1,000
Professional Contractors	$19,491,000	$1,013
Ship/marine Craft	$60,000	$1,091

Note: First Year Costs are in Appendix C

ED_001625_00032151-00045

Costs: Methylene Chloride PPE

(Regulatory Option #2)

- Do you have a ventilation system installed? If not, would it be feasible for you to install one?
- Do you have experience with workers using personal protective equipment such as air-supplied respirators?
- How much would ventilation and local exhaust systems cost for your workspace?
- What are your experiences with exposure reduction for workers? For example:
    - Installing or updating ventilation and local exhaust
    - Installing or operating other engineering controls
    - Equipment changes to reduce exposures
    - Monitoring worker exposures to chemicals in the air
    - Air-supplied respirators
    - Specialized gloves (such as Silver Shield)
    - Other personal protective equipment
    - Worker training to reduce exposures

ED_001625_00032151-00046

Analyzing Potential Regulatory Options for NMP

- From over 50 options analyzed, the two options presented today would provide risk reduction to target benchmarks
- Other options considered **do not** reduce exposure to benchmark risk levels

Option	Why it does not provide sufficient risk reduction
Limiting concentration of NMP in a formulation	Even when reduced to 25% concentration, for typical work scenarios (>4 hours), workers without PPE would be at acute risk
Prohibiting certain formulations (such as brush-on) to reduce dermal exposure	Most acute and chronic risk would remain
Requiring local exhaust or other ventilation (without personal protective equipment)	Alone, this would not be sufficient. Dermal protection (gloves) would be needed.
Requiring PPE (specialized gloves) and respirator (APF 10)	Alone, PPE is not enough to reduce risks for a full-workday exposure. Formulation changes would be needed.
Requiring record keeping and testing	Alone, this does not provide protection from risks
Requiring labeling of products	The particular actions the label would need to require are not likely to be followed properly. For an example, see the Riley, et al. article referenced in Appendix F. Alone, exposures would not be reduced to benchmark risk levels.

Potential Regulatory Options- NMP

1. Regulatory Option #1: Prohibit manufacturing, distribution, and use of NMP as a paint remover
2. Regulatory Option #2: Allow certain commercial use with worker protections and other restrictions to protect the public
   - Worker protections
     - Formulation requirements: No more than 25% NMP in paint remover products
       - Even when gloved, workers were found to be at risk when using high-concentration products for 8 hours
     - Gloves:
       - Formulators must test their formulated product to determine which gloves would be protective. Glove breakthrough varies, depending on which co-solvents are present.
       - Formulators must label their products and SDS with the information about gloves
       - Gloves may not be re-worn; must be replaced after each 8-hour shift (minimum)
     - Respiratory protection: In addition to gloves, respiratory protection would be required. This could be achieved by:
       - A respirator of APF 10 (worker only, not bystanders)
       - Workplaces may meet an air exposure limit of 8 ppm. Ventilation or engineering controls could be used to meet the air exposure limit.
   - Other requirements
     - Packaging requirements: Products would be packaged in volumes no less than 55-gallon drums, to prevent consumer misuse
     - Downstream notification of these requirements by manufacturers and formulators.

ED_001625_00032151-00048

Risk Reduction of Potential Regulatory Options - NMP

Reg. Option #	Regulatory Option description	Risk Reduction as a Result
1	Prohibit manufacturing, distribution, and use of NMP as a paint remover	Risks eliminated. This option provides complete risk reduction.
2	Allow certain commercial uses with worker protections (such as product reformulation and gloves) and other requirements to protect the public (such as packaging requirements)	Assuming that PPE is used as required for efficacy, this reduces risks to benchmarks for workers and for occupational bystanders (other workers). See additional details on next slides.

ED_001625_00032151-00049

Risk Reductions: NMP PPE Option

(Regulatory Option #2)

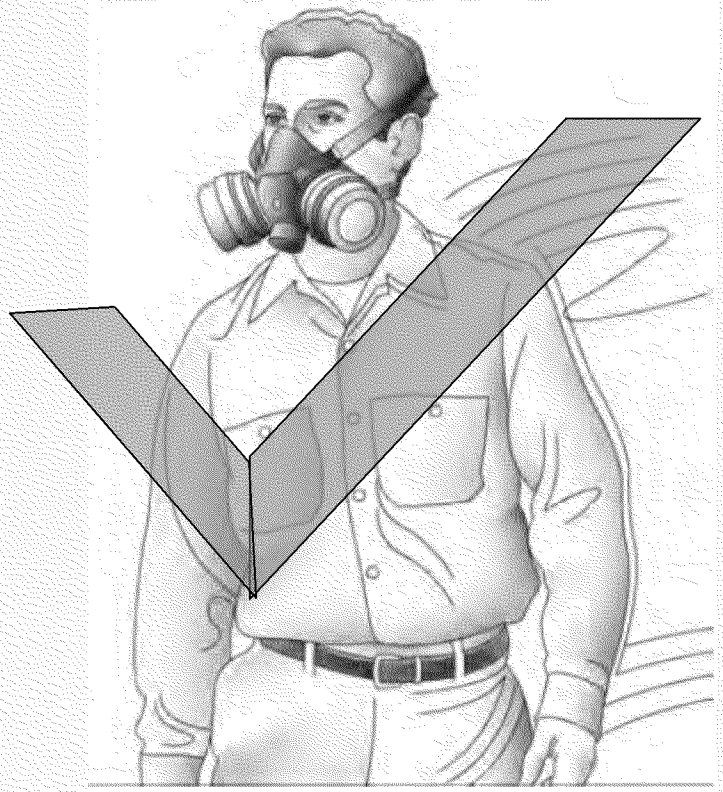
Scenario	Industry/ Activity	Exposure	PPE required to achieve MOE Greater Than the Benchmark MOE
Baseline (high end of current exposures)	Miscellaneous stripping	Acute	Not achievable
		Chronic	Not achievable
	Graffiti removal	Acute	Not achievable
		Chronic	Not achievable
With Maximum 25% NMP in products and no ventilation indoors	Miscellaneous stripping	Acute	Gloves
		Chronic	Gloves + APF 10
	Graffiti removal	Acute	Gloves
		Chronic	Gloves

- In all scenarios evaluated, without gloves and without a respirator or ventilation there are risks of concern.
  - In some scenarios (indoors) the MOE with gloves and APF 10 is greater than the benchmark MOE and "gloves + APF 10" is shown in the table signifying no significant risks when wearing gloves.
  - In some scenarios (outdoors) the MOE with gloves is greater than the benchmark MOE and "gloves" is shown in the table signifying no significant risks when wearing gloves.
  - Based on modeling and underlying assumptions, in some scenarios the exposure reduction of gloves combined with the most protective respirator (APF 10,000) would not reduce exposure sufficiently to achieve an MOE above the MOE baseline. In those cases "not achievable" is shown.
- Refer to Table 2-3 in the Final Risk Assessment for exposure durations and air concentrations used to assess risks.
- Protective gloves assumed 90% effective to account for actual use situations (physical stress on gloves, incidental exposure around gloves, enhanced absorption under gloves)

ED_001625_00032151-00050

Examples of Respirators with APF 10

Half mask/Dust mask
APF=10
Needs to be fit tested



Half mask (Elastomeric)
APF=10
Needs to be fit tested

For more information, see Appendix H or https://www.osha.gov/Publications/3352-APF-respirators.pdf

Costs: NMP Prohibition

(Regulatory Option #1)

- Costs include costs to manufacturers, processors and to users
- Changing products to remove NMP (chemical substitution in formulation, relabeling, and other changes) *(applies to manufacturers, processors)* + downstream notification about prohibited uses *(applies to manufacturers, processors, distributors)*
  - 6 manufacturers, 14 formulators
  - First-year costs: $316,000, or annualized cost: $20,000 (over 20 years)
- Costs associated with switching to substitutes *(commercial users)*
  - Materials replacement *(commercial users)*
    - Commercial costs: $728,000 annually (Cost of switching to an alternative chemical paint remover)
    - Depending on the job, the time needed could increase or decrease. This is based on the type and number of coatings, surface prep, clean-up, dwell time, and other factors
  - Process change for substitutes *(commercial users)*
    - For some firms this is expected to be minimal if they have experience with using alternative chemicals or paint removal methods.
    - Other firms will likely have a trial and error period until they find an alternative chemical or mechanical means that meets the needs of their work process.
  - Hazards of substitutes
    - Substitutes present some hazards, but generally less than NMP
- **Total cost (for all commercial users):**
  - **$728,000** + inconvenience and hazards of substitutes
  - First year monetized costs: $316,000

Costs: NMP Reformulations & PPE Option

(Regulatory Option #2)

- Costs include costs to manufacturers, processors and to users
- Changes to product formulation, relabeling, and other changes *(manufacturers, processors)* + downstream notification *(manufacturers, processors, distributors)*
  - 6 manufacturers, 14 formulators
  - First-year costs: $316,000, or annualized cost: $20,000 (over 20 years)
- Commercial users (total costs and for small businesses)
  - Total Annualized Cost: $4.7 million
    - Cost per employee of worker PPE of air supplied respirator (APF 10)
      - Device & fitting costs included ($178 per worker, per year)
      - PPE training costs included ($252 per worker, per year)
      - Medical monitoring costs included ($212 per worker, per year)
    - Specialized glove cost included, assumption gloves are only good for 8 hours (one work day due to uncertainty of permeability of various product formulations) ($7.74 per glove pair, assumes bulk purchase of gloves)
    - Other engineering, equipment changes, or LEV controls would be applicable under this option but are not included in the cost estimate due to lack of data

ED_001625_00032151-00053

Costs: NMP Reformulation & PPE Option

(Regulatory Option #2)

Industry Sector	Total Annualized Cost	Cost Per Small Firm
Aircraft	Not used in this industry	$0/not applicable
Art Restoration & Conservation	$83,000	$275
Automotive	$2,000	$186
Bathtub Refinishing	Not used in this industry	$0/not applicable
Furniture Refinishing	$840,000	$543
Graffiti Removal	$1,306,000	$608
Professional Contractors	$2,437,000	$913
Ship/marine Craft	Not used in this industry	$0/not applicable

Note: First Year Costs are in Appendix C

ED_001625_00032151-00054

Questions & Your Thoughts

- We would like to hear more about:
  - Methylene chloride, NMP, and your business
  - Exposure reduction for workers
  - Experiences with alternatives
- Do you have any advice for EPA?

Contact Information

- For paint removers rulemaking:
  - Niva Kramek, 202-564-2897, kramek.niva@epa.gov
  - Joel Wolf, 202-564-0432, wolf.joel@epa.gov
- For SBAR:
  - Nathaniel Jutras, RFA/SBREFA staff contact
    EPA Office of Policy
    202-564-0301
    Jutras.Nathaniel@epa.gov
- All Work Plan Chemical risk assessments: http://www.epa.gov/assessing-and-managing-chemicals-under-tsca/assessments-tsca-work-plan-chemicals

ED_001625_00032151-00056

List of Appendices

A. Questions to SERs
B. Regulatory History and International Action
C. Additional Cost Information
D. Information on the Efficacy of Paint Removers
E. Support from Department of Labor
F. Articles on Methylene Chloride in Paint Removal
G. Alternative Paint Removal Product List (SER request)
H. OSHA Assigned Protection Factors for the Revised Respiratory Protection Standard

ED_001625_00032151-00057